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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,403	12/20/2001	Ian Keith Hatton	P32162C1	6756

7590 01/21/2005

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EXAMINER

HUANG, EVELYN MEI

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/032,403	<b>Applicant(s)</b> HATTON ET AL.	
	<b>Examiner</b> Evelyn Huang	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 13-22 are pending. Claims 1-12 have been canceled in the preliminary amendment filed on 12-20-2001.

#### ***Election/Restrictions***

2. In response to the restriction requirement mailed on 9-3-2004, Applicants have elected with traverse the invention of Group I, and the compound of Example 3 of page 19 as the elected species. Claims of Group II and Group III are withdrawn from further consideration as being drawn to the non-elected inventions.

Applicants argue that claims 13-22 of the present invention read upon a plurality of distinct, but related inventions and fully comply with the unity of invention requirement according to the PCT, and cannot, therefore, be further subdivided or restricted and must be included in a single application, as the compounds of the present invention has a single mode of action as antibacterial agents.

On the contrary, the only common structure in the instant is the piperidinyl. The naphthyridine compound of Group I, the quinazoline compound of Group II, and the cinnoline compound of Group III would not have been of sufficient structural similarity to allow for the Markush grouping exhibiting utility, absent some teaching of equivalence in the prior art. Indeed, compounds having the same piperidinyl core has been shown to be therapeutic agents for treating cardiovascular diseases (Trijzelaar, 4472403).

As pointed out by the Applicants, Group II should be quinazoline and Group III should be cinnoline. Correction is hereby made.

#### ***Priority***

3. This application is a continuation of 09/807275. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and

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(a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

The priority document is not in the file. Applicant is requested to submit a copy of the foreign priority document with the response.

### *Specification*

4. The abstract on separate sheet (not the first page of the corresponding PCT) is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 13, 19-22, the term 'derivative' in 'pharmaceutically acceptable derivative' is open-ended and is therefore indefinite.
- b. Claim 15, it is recommended that 'most preferably methoxy' be deleted from claim 15, and methoxy be claimed separately in a claim dependent on claim 15.
- c. Claim 20,
  - (a), definition of M in 'X is M' is not described in the claim.
  - (b), "converting R<sup>11'</sup>, R<sup>1'</sup>, R<sup>2'</sup>, R<sup>3'</sup> and R<sup>4'</sup> to **R<sup>11'</sup>**, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup>" should be "converting R<sup>11'</sup>, R<sup>1'</sup>, R<sup>2'</sup>, R<sup>3'</sup> and R<sup>4'</sup> to **R<sup>11'</sup>**, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup>".

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- (b), the metes and bounds of 'groups convertible thereto' in 'R<sup>11</sup>, R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup> and R<sup>4</sup> or groups convertible thereto' is unclear as it reaches out to as yet unidentified groups.
- (b), the metes and bounds of the conversion of one substituents to the other substituents is unclear in view of the large number of diverse substituents within each variables, and that some of the processes of conversion are not readily available.

The rejection is applicable to claims dependent on the above claims.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 13-17, 20-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/477900. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound wherein R5 is 4-fluorobenzimidazolyl, benzo-thiadiazolyl or quinoxalinyl as recited in copending claim 8, the 4<sup>th</sup> compound from the top or the 4<sup>th</sup> compound from the last of copending claim 9, is encompassed by the instant compound wherein R5 is heteroarylalkyl.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 13-17, 20-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/484563. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending compound has an alkoxycarbonyl or aminocarbonyl R3 substituent at the 4<sup>th</sup> position whereas the instant R3 is in the 2<sup>nd</sup> or 3<sup>rd</sup> position of the piperidiny. The instant is therefore the positional isomer of the copending compound. Positional isomers have been held prima facie obvious because compounds of close structural similarity are expected to have similar properties. In re Crounse, 150 USPQ 554; In re Mehta, 146 USPQ 284; In re Jones, 74 USPQ 149.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 13-16, 18, 20-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6602882. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The antibacterial compound, 1-heptyl-4-[N-6-methoxyquinoline-4yl)-aminocarbonyloxy]-piperidine of claim 7 in the patent differs from the instant in being a quinolinyl with aminocarbonyloxy instead of the 1, 5-naphthyridinyl with aminocarbonyloxyethyl (i.e. A is NR<sup>11</sup> (R<sup>11</sup> = methyloxycarbonyl), B=CR<sup>8</sup>R<sup>9</sup> (R<sup>8</sup>, R<sup>9</sup> =H), n=0). However, quiniolinyl and 1,5-naphthyridinyl are optional choices (column 16, claim 2; claim 7). Furthermore, aminocarbonyloxy and the aminocarbonyloxyethyl are also optional choices (column 16, n=0, 1, or 2).

At the time of the invention, one of ordinary skill in the art would be motivated to modify the patented species compound as taught in the patent to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful as an antibacterial agent.

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*Allowable Subject Matter*

10. Claims 13-22 are objected to because they contain non-elected subject matter.

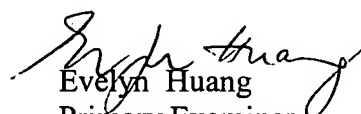
The inventive compound, the composition and method of use thereof would be allowable upon overcoming the 112 second paragraph rejection and the obviousness type double patenting rejections.

Trijzelaar (4472403) discloses a quinolinyl-piperidinyl compound for treatment of cardiovascular disease. The instant, however, is a naphthyridinyl antibacterial compound. Absent is the motivation to modify the compound of Trijzelaar's compound to arrive at the instant invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
Art Unit 1625